CLAIMS

1. An immunoglobulin product which is obtainable by a process for purifying immunoglobulin, i.e. immunoglobulin G (IgG), from a crude immunoglobulin-containing plasma protein fraction, which process comprises the steps of:

(a) preparing an aqueous suspension of the crude immunoglobulin-containing plasma protein fraction;

(b) adding a water soluble, substantially non-denaturating protein precipitant to the said suspension of step (a) in an amount sufficient to cause precipitation of a high proportion of non-immunoglobulin G proteins, aggregated immunoglobulins and particles including potentially infectious particles such as virus particles, without causing substantial precipitation of monomeric immunoglobulin G, thereby forming a mixture of a solid precipitate and a liquid supernatant;

(c) recovering a clarified immunoglobulin G-containing supernatant from the mixture of step (b);

(d) applying the clarified immunoglobulin G-containing supernatant of step (c) to an anion exchange resin and subsequently a cation exchange resin;

(e) washing out protein contaminants and the protein precipitant from the cation exchange resin of step (d) with a buffer having a pH and ionic strength sufficient to re move the contaminants from the resin without causing substantial elution of immunoglobulin G;

(f) eluting immunoglobulin G from the cation exchange resin of step (e) with a substantially non-denaturating buffer having a pH and ionic strength sufficient to cause efficient elution of the immunoglobulin G, thereby recovering an immunoglobulin G containing eluate;

(g) performing a dia/ultrafiltration on the immunoglobulin G-containing eluate of step (f) to concentrate and/or dialyse the eluate, and optionally adding a stabilizing agent, thereby forming a concentrated and/or dialysed and optionally stabilized product;

(h) adding a virucidal amount of virus-inactivating agent to the immunoglobulin G-containing dia/ultrafiltrated and optionally stabilized fraction of step (g) resulting in a substantially virus-safe immunoglobulin G-containing solution;

(i) applying the immunoglobulin G-containing solution of step (h) to an anion exchange resin and subsequently to a cation exchange resin;

(j) washing the cation exchange resin of step (i) with a buffer having a pH and ionic strength sufficient to wash out the protein contaminants and the virus-inactivating gent from the resin without causing substantial elution of immunoglobulin G;

(k) eluting immunoglobulin G from the cation exchange resin of step (j) with a substantially non-denaturating buffer having a pH and ionic strength sufficient to cause efficient elution of the immunoglobulin G, thereby recovering an immunoglobulin G containing eluate; and

(l) subjecting the immunoglobulin G-containing eluate of step (k) to dia/ultrafiltration to lower the ionic strength and concentrate immunoglobulin G of the solution, and adjusting the osmolality by adding a saccharide.

2. A product obtainable by the process described in claim 1, wherein the anion exchange resin and the cation exchange resin in step (d) and/or step (i) are connected in series.

3. A polyclonal immunoglobulin product having the following characteristics:

a) a purity of more than 98%,

b) a content of IgG monomers and dimers of more than 98.5%,

c) a content of IgA less than 4 mg of IgA/l,

d) a content of IgG1, IgG2, IgG3 and IgG4, and

e) a content of polymers and aggregates less than 0.5%.

4. An immunoglobulin product according to claim 3 which does not comprise detergent, PEG or albumin as stabilizer.

5. An immunoglobulin product according to claim 3 which contains less than 3 mg/l IgA.

6. An immunoglobulin product according to claim 3 which contains between 55 and 65% IgG1, between 30 and 40% IgG2, between 2 and 5% IgG3 and between 1 and 4% IgG4.

7. An immunoglobulin product according to claim 3 which is a liquid product.

8. An immunoglobulin product according to claim 3 for instant intravenous administration.

9. An immunoglobulin product according to claim 3 for use in medicine.

10. A medicinal product which comprise a pharmaceutically acceptable carrier and an immunoglobulin product according to claim 3.

11. A method of treating a mammal with PID (Primary Immune Deficiency), SID (Secondary Immune Deficiency), ITP (Idiopathic Thrombocytopenic Purpura), polyradiculitis, peripheral polyneuropathies, Kawasaki's disease, polymyositis, severe chronic autoimmune disease, chronic inflammatory demyelinating polyneuropathy (CIDP), multifocal motoric neuropathy, multiple sclerosis, Myasthenia Gravis, Eaton-Lambert's syndrome, Opticus Neuritis, epilepsy, Abortus habitualis, primary antiphospholipid syndrome, rheumatoid arthritis, systemic lupus erythematosus, systemic scleroderma, vasculitis, Wegner's granulomatosis, Sjogrens syndrome, juvenile rheumatoid arthritis, autoimmune neutropenia, auto-immune haemolytic anamia, neutropenia, Crohn's disease, colitic ulcerous, coeliac disease, asthma, septic shock syndrome, chronic fatigue syndrome, psoriasis, toxic shock syndrome, diabetes, sinusitis, dilated cardiomyopathy, endocarditis, artherosclerosis, AIDS or a bacterial infection, the method comprising administering to the mammal an immunoglobulin product according to claim 1 or 3.

12. A method according to claim 11 wherein the mammal is a human being.